

REMARKS

Claims 9-11 and 14-17 are pending in the present application and are rejected. Claims 9 and 15 are herein amended. No new matter has been added. Applicants thank the Examiner for the courtesies extended in the telephone interview of October 26, 2009. Applicants' Statement of the Substance of the Interview is incorporated herein.

Preliminary Comment

As a preliminary matter, Applicants note that none of the previous Office Actions have acknowledged the claim for foreign priority or acknowledged receipt of the priority document. Applicants respectfully request that the next Office communication clarify this by checking boxes 12, 12(a) and 12(a)(3).

Applicants' Response to Claim Rejections under 35 U.S.C. §112

Claim 15 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is the position of the Office Action that claim 15 is unclear as not claiming a complete method. The Office Action states that "in addition to alternative soaking, the method should require a step of alternatively soaking to produce a gradient of calcium phosphate." However, claim 15 already recites the step of "alternative soaking." The only two essential steps in the method are providing the biomaterial and alternatively soaking the second side of the

biomaterial. There are no essential steps omitted. As explained in the telephone interview, the production of the gradient of calcium phosphate is *an inherent result of* the alternative soaking, and is not a separate step.

However, in order to expedite examination, Applicants herein amend the “alternatively soaking” step of claim 15 to recite “whereby a gradient of calcium phosphate is formed that varies in the biodegradable polymeric material from the first side of said biodegradable polymeric material to the opposite second side of the biodegradable polymeric material with an increasing linear gradient.” Applicants respectfully submit that this clarifies that the production of the gradient of calcium phosphate is *an inherent result of* the alternative soaking step. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

Claims 9-11 and 14-17 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Mattern et al. (6,969,523) or Yannas et al. (4,947,840) in view of Akashi et al. (6,387,414) and Sherwood et al. (6,454,811), and if necessary in further view of Taguchi et al. (Biomaterials).

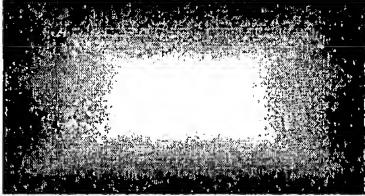
It is the position of the Office Action that Mattern or Yannas discloses the embodiment as claimed with the exception of forming the composite by alternatively soaking the material in a calcium ion-containing solution and a phosphate ion-containing solution. The Office Action relies on Akashi to provide this teaching. The Office Action additionally relies on Sherwood to teach a gradient generally. The Office Action also optionally relies on Taguchi to teach

alternative soaking of a film in a calcium ion-containing solution and a phosphate ion-containing solution.

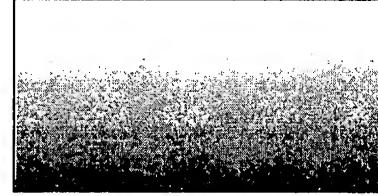
As recognized by the Office Action, Akashi discloses alternatively soaking an entire biomaterial material in two solutions. In particular, the Office Action states that “when soaking the whole material as disclosed by Akashi and Taguchi, the surface of the whole material contacted with the alternative soaking solution has the greater amount of calcium phosphate as when the second side is contacted with the alternative solutions.” See page 7.

With respect to this point, Applicants herein clarify the difference between a material which is entirely alternatively soaked and a material which is alternatively soaked on one side. The following illustrations are conceptual drawings of these different materials.

Alternatively soaking entire material



Alternatively soaking only a single side of material



In these illustrations, the darker part illustrates the highest concentration of calcium phosphate.

These two different types of gradients are not only structurally different; they are also used for entirely different applications. Specifically, the difference between an implant entirely soaked and an implant soaked on one side is that an implant entirely soaked can only be used as an implant in one type of tissue, such as hard tissue (*i.e.*, bone). Meanwhile, an implant soaked on only one side can be used to interface between two types of tissue, such as hard tissue (*i.e.*, bone) and soft tissue (*i.e.*, cartilage). As such, an implant which is entirely soaked could be used

as an implant *within* a bone, such as within a femur or ilium, for example. On the other hand, an implant which is soaked only on one side can be used as an implant near a joint, such as a knee joint, for example. Such an implant would be an interface between bone tissue on one side and a soft tissue, such as cartilage, a tendon or a ligament, on the other side.

In the previous Office Action, it was stated that the previously filed amendment “urges that Akashi et al do not produce a gradient since the entire matrix is alternatively soaked.” However, Applicants submit that this is a mischaracterization of their remarks. Applicants did not intend to argue that Akashi does not produce a gradient. On the contrary, Applicants stated that “[t]he soaking disclosed in the cited art necessarily imparts the structural feature of a gradient which increased toward the exterior of the material—in other words, adsorption.” See page April 23, 2009 filing, page 9. Thus, Applicants did not argue that Akashi does not produce a gradient—rather, Applicants urged that the cited art does not disclose a gradient as claimed—a gradient from a first side of said biodegradable polymeric material to a second side of said biodegradable polymeric material with an increasing linear gradient. However, in the telephone interview, the Examiner indicated that the claims could be improved by clarifying that the gradient is from a first side to an *opposite* second side. Applicants herein amend the claims to clarify this point. Applicants respectfully submit that this subject matter is supported at least by page 11, lines 19-27, page 12, lines 9-19 and Figure 1.

Next, Applicants discuss the cited art in greater detail. Each of Mattern and Yannas appear to disclose a biodegradable polymeric material as claimed. Akashi appears to disclose a biodegradable polymeric material as claimed, which is alternatively entirely soaked in the two

solutions, resulting in a gradient towards the center. As to Akashi, since the material is entirely soaked, the gradient formed is not the gradient *as claimed*. Further, there is no reason why one having ordinary skill in the art would modify Akashi to only soak a single side of the material, which would be required to achieve the gradient *as claimed*.

As noted above, Taguchi also appears to disclose alternative soaking of a material. However, Applicants respectfully submit that Taguchi is at best duplicative of Akashi and at worst irrelevant to the claimed embodiment. Like Akashi, Taguchi discloses alternative soaking of an entire material. However, in Taguchi, the material which is soaked is a polyethylene film. Such a polyethylene film is completely different from biodegradable polymeric material such as glycosaminoglycan, collagen, or a crosslinked product of glycosaminoglycan and collagen. Notably, immersion solutions cannot diffuse into polyethylene, and thus, a gradient of any kind cannot be formed. As such, Applicants respectfully submit that the combination of Mattern, Yannas, Akashi and Taguchi does not disclose or suggest the embodiment as claimed.

Finally, Applicants discuss Sherwood, which is the only reference which appears to disclose a gradient remotely resembling the gradient as claimed. However, as mentioned in previous communications, Sherwood achieves the gradient by a completely different method than in the claimed embodiments or Akashi. In the claimed embodiments and Akashi, the gradient is achieved by alternative soaking of the material in the two solutions (as noted above, in Akashi, the entire material is soaked; in the claimed embodiments one side is soaked). On the other hand, in Sherwood, the gradient is achieved by three-dimensional printing (3DP). This is an entirely different process from soaking, and involves complications such as milling a material

down to a powder and then “printing” the material using a dispenser. As such, Applicants respectfully submit that one having ordinary skill in the art would have had no reason to combine Sherwood with the other cited references in any way.

Applicants respectfully submit that proposed modification of the cited art relies merely on impermissible hindsight. There is no rationale in the cited art as to reasons why one skilled in the art would modify the combination of Mattern/Yannas and Akashi to include alternative soaking of a single side of the material such that a gradient *as recited* is formed. The disclosure of Sherwood would not be a proper rationale for one skilled in the art to do this, since Sherwood’s method is entirely different from that of Akashi. Rather, the only rationale to modify the cited art as proposed is found in the Applicants’ disclosure itself. This is impermissible. As such, Applicants respectfully submit that the method and apparatus as claimed would not have been obvious to one skilled in the art, and that the rejection should therefore be withdrawn. Therefore, for at least the above reasons, Applicants respectfully submit that the combination of cited art, either singly or in combination, does not disclose or suggest the embodiments as claimed. Favorable reconsideration is respectfully requested.

Claims 9, 15, 16, and 17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Akashi et al.

It is the position of the Office Action that Akashi discloses the embodiments as claimed, with the exception of teaching using collagen as a matrix. The Office Action argues that it would have been obvious to modify Akashi to use collagen as a matrix.

In response, Applicants respectfully submit that these claims are patentable over Akashi for similar reasons as to why they are patentable over the combination of Mattern/Yannas, Akashi, Sherwood, and optionally, Taguchi. That is, the cited art does not disclose or suggest a material having the gradient as claimed or a method for producing such a material. Favorable reconsideration is respectfully requested.

Claims 10, 11 and 14 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Akashi et al. in view of Mattern et al. or Yannas et al.

It is the position of the Office Action that Akashi discloses the embodiments as claimed, with the exception of teaching that the polymeric material is a crosslinked product of glycosaminoglycan and collagen. The Office Action relies on Mattern or Yannas to provide this teaching. Favorable reconsideration is respectfully requested.

In response, Applicants respectfully submit that these claims are patentable over Akashi for similar reasons as to why they are patentable over the combination of Mattern/Yannas, Akashi, Sherwood, and optionally, Taguchi. That is, the cited art does not disclose or suggest a material having the gradient as claimed or a method for producing such a material. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Application No. 10/516,818
Art Unit: 1657

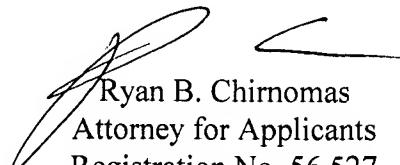
Amendment
Attorney Docket No. 043070

If the Examiner deems that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp